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Regulations (Preambles to Final Rules)

IV. Mineralogical Considerations

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- **Record Type:** Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite
- **Section:** 4
- **Title:** IV. Mineralogical Considerations

IV. Mineralogical Considerations

The following is a discussion of the mineralogical evidence submitted to this record concerning defining and differentiating the types of minerals commonly designated as "asbestos", "asbestiform" and "non-asbestiform". OSHA's position, expressed in the proposal and in the 1986 standards, was that precise mineralogic definitions are helpful in describing the scope of the standard, but absent strong evidence that mineralogic distinctions are biologically relevant, such distinctions by themselves, should not dictate regulatory health based decisions. In the 1986 standards, OSHA defined "asbestos" and "non-asbestiform ATA" separately, but covered both varieties based on health effects evidence.

Much evidence and testimony in this proceeding related to the extent to which different mineral varieties can be distinguished . OSHA's overall regulatory approach to this issue is shaped by its mandate to protect employee health, and to err on the side of protection when presented with a close scientific question. The Agency believes that mere difficulties in differentiating between these mineral varieties should not dictate uniform regulatory treatment, unless such difficulties reflect the fact that the varieties, in biologically relevant respects, behave the same. Of course, misidentification of mineral type affects the confidence in and usefulness of studies reporting the biological potential of different mineral types. Also, the extent of analytical difficulty in distinguishing even well characterized mineral types, would be relevant to OSHA in making feasibility determinations concerning analytic methods.

In general there was agreement concerning the broad definitions of these mineral classifications. Thus, asbestos is not a precisely defined chemical compound, but rather, a collective term given to a group of similar silicate minerals having commercial significance. Historically six silicate minerals have made up the group of minerals which has been collectively referred to as Asbestos. These six minerals are chrysotile, crocidolite, amosite (which is mineralogically known as cummingtonite - grunerite asbestos), tremolite asbestos, anthophyllite asbestos, and actinolite asbestos. Chrysotile belongs to the family of minerals called serpentine minerals. The remaining five minerals belong to the family of minerals called amphiboles.

Dr. Arthur Langer pointed out in his testimony and comments to OSHA, that the definition of

asbestos is comprised of a mineralogical definition and an economic geology definition. Langer states:

Asbestos is described in the mineralogical literature as several silicate minerals with the following characteristics: Minerals occurring in nature as fibers; Fibers are bundles composed of "hair-like" (filiform) fibrils, each with a high length-to-width ratio; Fiber bundles are polyfilamentous and the fibril strands may be easily separated by hand. Unit fibrils cannot be resolved by [the] unaided eye; ...In addition to the mineralogical criteria, the economic geology literature contains additional descriptive terms, mostly pertaining to properties exhibited by asbestos which render it useful in commerce. Among these are: fibers exhibit stability in acids and alkalies; act as electrical insulators; act as thermal insulators; fibers are highly flexible and can be woven into asbestos cloth or rope; fibers possess diameter dependent high tensile strength. Together, both geological disciplines have defined what asbestos is mineralogically. (Ex. 517, Tab 5)

Dr. Ann Wylie, testified that "Asbestos is a commercial term applied to a group of highly fibrous silicate minerals that readily separate into long, thin, strong fibers of sufficient flexibility to be woven, are heat resistant and chemically inert, and possess a high electrical insulation and therefore are suitable for uses where incombustible, nonconducting, or chemically resistant material is required." (Ex. 479-23).

Similarly, the Bureau of Mines stated in comments to the NPRM that a correct mineralogical definition of asbestos was:

A term applied to six naturally occurring serpentine- and amphibole-

group minerals that are exploited commercially because they crystallize into long, thin, flexible fibers that are easily separable when crushed or processed, can be woven, are resistant to heat and chemical attack, and are good electrical insulators. The six serpentine- and amphibole-group minerals commonly referred to as asbestos are chrysotile, cummingtonite-grunerite asbestos (amosite), riebeckite asbestos (crocidolite), anthophyllite asbestos, tremolite asbestos, and actinolite asbestos (Ex. 478-6).

The above minerals which are collectively termed asbestos, are also described as being asbestiform. Asbestiform is a mineralogical term describing a particular mineral habit. The habit of a mineral is the shape or form a crystal or aggregate of crystals take on during crystallization and is dependent on the existing environmental/geological conditions at the time of formation. The National Stone Association (NSA) and the American Mining Congress (AMC)state that, "The asbestiform habit can be defined as a habit where mineral crystals grow in a single dimension, in a straight line until they form long, thread - like fibers with aspect ratios of 20:1 to 100:1 and higher. When pressure is applied, the fibers do not shatter but simply bend much like a wire. Fibrils of a smaller diameter are produced as bundles of fibers are pulled apart. This bundling effect is referred to as polyfilamentous." (Ex. 467) Dr. Wylie testified that the asbestiform habit can be recognized by certain characteristics using light microscopy. For example she testified that:

Populations of asbestiform fibers, and this would include all, not just commercial asbestos, but all asbestiform fibers that I have looked at, they have mean aspect ratios greater than twenty to one for particles longer than five microns -- and again, it's very important that we qualify, when speaking of aspect ratio, length, because aspect ratio by itself as a population

characteristic has no meaning -- very thin fibrils that are usually less than half a micrometer in width. And you will see in any population of asbestiform fiber[s] at least two of the following characteristics. Normally they are all present, but two, I think is enough to convince me. Parallel fibers occurring in bundles, fibers displaying splayed ends, the matted masses of individual fibers, and fibers showing curvature. (Tr. 5/9, p. 92)

However Dr. Wylie emphasized that these are characteristics which apply to populations of asbestiform fibers and not a particular particle. She states that "The characteristics that were listed were population characteristics, not characteristics on a fiber by fiber discriminator. They weren't meant to say a particular particle must meet all these criteria in order to say that this is an asbestos particle or population present. And that's the way that definition is approached that if we have a bulk sample, and we are looking in that sample for the presence of -- asbestos," (Tr. 5/8, p. 144) In further clarification of the asbestiform habit Dr. Tibor Zoltai, a professor of mineralogy at the University of Minnesota, states that:

The development of the asbestiform properties is a gradual process, [and] depends on the extent of the appropriate conditions of crystallization. Consequently, there are variable qualities of asbestiform fibers. The poor quality asbestiform fibers of amphiboles are called byssolite, or brittle asbestos. The high quality asbestiform fibers because of their highly developed flexibility, strength and physical - chemical durability, constitute desirable industrial materials and are exploited under the generic term of asbestos. Although practically all amphiboles and most other minerals are known to occur in asbestiform habit, only a few amphiboles are known in sufficient concentration and quantity to produce commercial asbestos:... (Ex. 546).

Thus, asbestos is a collective term composed of both mineralogical and economic elements which has been used to refer to a specific set of asbestiform minerals which are, or were in the past, regarded as being commercially significant. The term asbestiform is a mineralogical term used to refer to those minerals which are found in a particular mineral habit. That is, while all asbestos is asbestiform, not all asbestiform minerals are asbestos.

As the above discussion shows, the term "asbestos" is based on more than mineralogic criteria, and its meaning also reflects to a certain extent the interests of the affected commercial communities. Non-asbestiform mineral varieties have a different commercial history. For the most part, they have had little commercial significance. This is related to their different crystallization habit. Because, unlike asbestos, they do not grow unidirectionally, into long thin fibers, therefore they often do not possess properties such as weavibility or high tensile strength which make them valuable for asbestos - like uses. For the most part non-asbestiform minerals are not mined for any special property, but rather, they are mined generally with other minerals as a basic stone product. However, non-asbestiform tremolite when mined with talc, results in enhanced usefulness to industries such as ceramic manufacturing, because of the other properties specific to non-asbestiform minerals.

The record makes clear, that from a mineralogic perspective the crystallization growth pattern of these minerals determines whether they develop as asbestos, or as non-asbestiform varieties. In joint comments to the record, the NSA and the AMC stated that "in the non-asbestiform variety crystal growth is random, forming multi-dimensional prismatic patterns. When pressure is applied, the crystal fractures easily, fragmenting into prismatic particles. Some of the particles or cleavage fragments are acicular or needle - shaped as a result of the tendency of amphibole minerals to cleave along two dimensions but not the third" (Ex. 467).

In his comments to the record, Dr. Zoltai notes that: Both asbestiform and non-asbestiform amphibole minerals have the same chemical composition and crystal structure. They are not distinguishable by instrumental analysis and x-ray diffraction. The difference between them is in their respective crystallization habit, that is, in their respective condition of crystallization. Non-asbestiform prismatic crystals are the common crystal habits of amphiboles. The asbestiform crystallization habit is the unusual one, it requires unique temperature and pressure conditions inducing unidirectional and rapid crystal growth. (Ex. 446)

In the NPRM, OSHA stated that unlike asbestiform minerals, non-asbestiform minerals do not separate into fibrils but, during processes such as mining, milling and/or processing can be broken down into fragments resulting from cleavage along the minerals two or three dimensional plane of growth. OSHA also stated that particles thus formed, are generally referred to as cleavage fragments and these fragments may occur in dimensions equal to asbestiform fibers.

Various commentors agreed with OSHA's definition of a cleavage fragment but objected to OSHA's characterization that non-asbestiform cleavage fragments and asbestiform fibers occur in similar dimensions. In testimony to OSHA, Kelly Bailey, an Industrial Hygienist with Vulcan Chemical Company speaking for the NSA stated:

The NSA believes that this statement is deliberately misleading in that it fails to take into account the population characteristics of both cleavage fragments and asbestiform fibers. It is true that there are some cleavage fragments that may have dimensions of 10:1, 20:1 or higher in aspect ratio when examined with PCM and that there may be a few asbestos fibers that have low aspect ratio dimensions similar to cleavage fragments: however, to imply that cleavage fragments do not differ from asbestiform fibers in an observable, dimensional way is poppycock! (Ex. 479-23).

Similarly, in earlier testimony to OSHA during the rulemaking for the 1986 revised standards, Dr. Wylie stated :

A particle of any mineral which is formed by regular breakage is called a cleavage fragment. Mineralogically, a fiber or fibril is a crystal which has attained its shape through growth, in contrast to a cleavage fragment which has attained its shape through regular breakage. The shape of amphibole cleavage fragments is somewhat variable depending upon the history of the mineral sample. Some amphiboles when crushed will produce a population of particles which may have the average aspect ratio of 5 to 1 or 6 to 1, whereas other amphibole samples when crushed may produce a population of particles whose aspect ratios average closer to 8 to 1 or 10 to 1. And in almost any population of amphibole cleavage fragments, it is possible to find a few particles whose aspect ratios may extend up to 20 to 1 or perhaps even higher. Amphibole asbestos populations, on the other hand, are characterized by aspect ratios which are considerably greater than this." (Ex. 230, Docket # H-033c).

Dr. Ann Wylie reiterated her earlier opinions in the current rulemaking stating:

Throughout OSHA's Notice of Proposed Rulemaking, they imply that cleavage fragments are similar in size to asbestos fibers, and the distinctions between them are fuzzy. In most cases, this is simply not so. Asbestos crystallizes from a fluid medium; growth takes place rapidly in one direction; the chemical makeup of the fluid may inhibit growth laterally. ...These

fibrils are single or twin crystals and they have very, very narrow widths and long lengths. It is the narrow width and long lengths that give asbestos flexibility and high tensile strength. Fibrils share a common axis of growth, but they are randomly [ar]ranged in the direction perpendicular to the fiber axis, and when disturbed, they are easily desegregated. Because their origin is different, population of cleavage fragments and fibers of the same minerals are simply different. Dr. Wylie adds that: While, there may be some cleavage fragments that cannot be distinguished from asbestos solely on dimensions, and there are some particles in asbestos samples that can't be distinguished from cleavage fragments, the populations are as wholes easily distinguishable. (Tr. 5/9, pp. 102-103)

As evidence of these differences Dr. Wylie cited to her paper entitled "An Analysis of the Aspect Ratio Criterion for Fiber Counting". Dr. Wylie testified:

As a part of the record, I have prepared a paper entitled "An Analysis of the Aspect Ratio Criterion for Fiber Counting: and that is part of OSHA's record. The paper reviews the distribution of aspect ratio for fiber and fiber bundles of amosite, crocidolite, chrysotile, and they clearly show that for those fibers and fiber bundles, again, that are longer than five micrometers, 100 percent or close to it, have aspect ratios greater than ten to one, and in every population that I have ever looked at that has the asbestiform habit, more than 50 percent have aspect ratios in excess of twenty to one...but most of them are 90 percent.

Also included in that paper are data from bulk and airborne samples of cleavage fragments, and there are cleavage fragments [with] aspect ratios greater than ten to one, and there are some that have aspect ratio[s] greater than twenty to one, but they are in much lower abundance, as a population. (Tr. 5/9, pp. 94-95)

While Dr. Wylie notes that there are differences in the distribution of aspect ratios when one looks at populations of asbestos fibers and non-asbestiform cleavage fragments, she also states that "aspect ratio is a dimensionless parameter" and "..it lacks information about the size particles; it only describes shape." (Tr.5/9, p. 95). Rather than aspect ratio, Dr. Wylie stressed that "width is a much more fundamental parameter of asbestos fibers, and perhaps will shed some light on how we tell particles that are elongated, whether they are cleavage fragments, or whether they are asbestos." (Tr. 5/9, p. 95).

To illustrate this point Dr. Wylie presented data in her testimony on the widths of various populations of asbestos fibers and non-asbestiform cleavage fragments from both bulk and airborne data (Transcripts, May 9, pp. 2-95 to 2-98). This data showed that in the populations of asbestos fibers she studied, the majority of fibers had widths less than one micrometer. For example, 85-90 percent the crocidolite fibers she studied had widths less than one micrometer and 60 percent had widths less than 0.5 micrometers. In amosite samples, greater than 90 percent had widths less than one micrometer and 75 percent had widths less than 0.5 micrometers. In tremolite asbestos samples, 85-95 percent of the fibers had widths less than one micrometer and 75 percent had widths less than 0.5 micrometers. Wylie stated that when looking at these fiber populations "... it really doesn't make any difference, much, whether you look at particles longer than five micrometers, or all particles in a population, when you look at width. Because of the nature of asbestos, width changes very little as length increases,..." (Transcripts May 9, p. 2-96). Dr. Wylie acknowledged, however, that asbestos fiber bundles may have widths greater than one micrometer, but she added that even in these cases the majority of particles are less than one micrometer.

Dr. Wylie was criticized for inconsistencies in her comparative population: i.e. sometimes

using all fibers, other times citing only those exceeding certain dimensions, e.g.longer than 5 micrometers. Dr. Wylie agreed that "depending upon which of those qualifiers you put forth, you get vastly different datasets. Now, I took all my cleavage fragment data and I first looked at the particles that are longer than five micrometers, and of these -- I'm just going to use a ten to one as aspect ratio -- 11 percent have aspect ratios greater than ten to one. If we look at that dataset... and only at the particles that have aspect ratios greater than three to one... and are longer than five micrometers, then we would say it's six percent are longer than five micrometers and have aspect ratios greater than ten to one. And finally if we look at particles that are both longer than five micrometers, and have an aspect ratio greater than three to one, we have 19 percent with aspect ratios greater than ten to one."(Tr. 5/9 at 106-107).

The record contains some additional, but less comprehensive evidence on comparative dimensions of non-asbestiform cleavage fragments and their asbestiform analogues. For example, in 1979, the Bureau of Mines compared 8 samples of ground tremolite of varying habit. It concluded that "based on this limited study, there is a relationship between the number of particles of "critical" dimensions, >10 um in length and < 0.5 um in width, and the habit of the tremolite - actinolite prior to grinding. ... Only the asbestos variety gave long, thin particles of the dimensions established by some medical scientists as necessary to produce adverse biological effects in laboratory animals. " (See RI 8367, p.17 as part of the NIOSH pre hearing submission Ex. 478-15).

A critical dimensional distinction between asbestiform fibers and ATA appears to be their widths. Thus, Dr. Wylie stated that her analyses of width show that "About 80 percent of the amphibole cleavage fragments longer than five micrometers, have widths greater than one micron, and none have widths less than 0.25." (Tr. 5/9, p. 98) Dr. Wylie also pointed out how the width of asbestos fibers will influence their aspect ratio. She states that "the mean width of asbestos fibers is less than half a micron, and if you have five micrometer particles, you have to have an aspect ratio of at least 10 to 1. (Tr. 5/9, p. 101-102). Moreover in her comments to the NPRM she states that "while low aspect ratio fiber (or fiber bundles) are present in asbestos populations, they are characteristic of short asbestos fibers...Since the mean width of asbestos fibers is less than 0.5 micrometers, the mean aspect ratio of a 5 micrometer fiber is about 10:1." (Ex. 479-23).

Dr. R.J. Lee, a microscopist and mineralogist with R.J. Associates, also noted the importance of width in distinguishing asbestos fibers from non-asbestiform cleavage fragments. Dr. Lee testified the following:

First asbestos -- airborne asbestos is less than one micrometer in diameter, unless it's present as bundles or cluster, which exhibit the characteristic fibrillar structure of asbestos, or as Dr. Wylie indicated, the hallmark of asbestos. Asbestos larger than a half a micron is a bundle --.

Second, non-asbestos particles longer than five micrometers in length are generally [more] than one micrometer in diameter, and only rarely less than half a micrometer in diameter. When larger than one micrometer in diameter, they do not exhibit the fibrillar structure of asbestos. (Tr.5/9 , pp. 114-115).

Similarly in their joint comments to the record the NSA and the AMC stated the following observations about particle width:

Due to the straight line fibrillar crystal growth of asbestos, the width of an asbestos fiber is

essentially independent of its length and is not easily altered by processing. In contrast, cleavage fragment populations show increasing width as particle length increases due to the characteristics imparted from normal three dimensional crystal growth. The result of this difference is cleavage fragments with widths rarely less than 0.5 micrometers and almost never less than 0.25 micrometers. Asbestos tends to show a high proportion of fibers less than 0.25 micrometers in width. (Ex. 467)

Dr. Charles Spooner, a microscopist and mineralogist with Charles Spooner and Associates Inc., concurred in his testimony that asbestos fibrils have widths less than 1 micrometer and that most cleavage fragments have low aspect ratio (Tr. 5/8, pp. 120-121). However he also noted that cleavage fragments may also have high aspect ratios. Dr. Spooner stated that "In the universe of amphibole cleavage fragments it seems likely that a greater proportion will exist as more or less equant bodies, however there will be those instances where high aspect ratio respirable cleavage fragments will be generated upon crushing of the amphibole bearing rock." (Ex. 512).

As noted earlier in this discussion, Dr. Wylie acknowledged that one may find a few cleavage fragments with high aspect ratios, but she added that populations of asbestos fibers and cleavage fragments, as a whole, are distinguishable from one another. However Dr. Spooner points out that "...from the industrial hygiene perspective, very often we are dealing with air samples. We are looking at an airborne fiber and trying to assess its respirability. And again, we are often in the industrial hygiene setting, we don't have the opportunity to know where the material is coming from, nor do we have the opportunity to look at a very large population of fibers..." (Tr. 5/8, pp. 117-118). Thus OSHA believes that while one can differentiate between mineral types when populations of particles are examined, when single, isolated particles are examined (e.g. particles from air samples) the ability to differentiate may become more difficult.

In the NPRM OSHA stated that at the microscopic level, on a particle by particle basis, differences in gross growth characteristics may not be readily observable. Similarly, Dr. Art Langer acknowledged that "...in some instances single, isolated particles may be impossible to distinguish, i.e. acicular cleavage fragment from asbestiform fibril" (Ex. 517, Tab 5). Dr. Langer also noted however that while there are some particles which defy mineralogical identification, the percentage of particles that comprise this group is a small percentage (Tr. 5/11, p. 230).

Identification of fibers is confounded by the existence of particles which do not fit a precise mineralogic definition. For example, some samples of industrial talc have been shown to contain "intermediate fibers." Dan Crane, a microscopist at OSHA's Salt Lake City Technical Center, describes these intermediate fibers which are found in industrial talc samples and notes that "It is only by a combined optical/electron optical approach can the nature of the intermediate fibers can be determined. Even at that, they defy definite description." (Ex. 410-23). Mr. Crane goes on to explain that:

When one looks at the industrial talcs in the microscope, he sees large numbers of particles that are much longer than 20 to 1 even to nearly 100 to 1 in aspect ratio. The first reaction is to say these are the asbestos fibers of tremolite and anthophyllite indicated by the known presence of those minerals in the products. Unfortunately, this is a false assumption. They are for the most part fibers of industrial talc. They have been dubbed intermediates by us, as talcboles by Malcom Ross and fibrous biopyriboles by David Veblan. What they are not is anthophyllite or tremolite. (Ex. 410-23)

In his description of these intermediate fibers Crane notes that examining these particles by light microscopy (e.g. using indices of refraction and dispersion oils) one would not call these particles anthophyllite. However when one use electron microscopy one would conclude that these particles are indeed anthophyllite. Mr. Crane explains why this difference occurs:

The fault can be corrected when the analyst realizes that in this particular mineral, the deposit was anthophyllite at one time. The particular mechanics of this are beyond the scope of this letter. Suffice it to say that it is being done in such a way as to leave the more major structure of the anthophyllite fibers intact while transforming them to talc. This residual structure has given rise to electron diffraction patterns that mimic amphibole patterns. Very careful measurement and calibration of these patterns reveal subtle strains in the structure leading to a mineral with similar features to talc and to anthophyllite and yet the numbers fall in between. ...I have described these other fibers because they are the fibers with the closest morphological similarity to asbestos. They do have splintering and bundle of sticks and frayed ends as characteristics. These are characteristics which we often ascribe to truly asbestiform minerals. All the samples we have examined have been crushed prior to our receiving them. Therefore, we cannot say whether they grew in nature as asbestos fibers. They do look like asbestos and if morphology is the major role in toxicity or carcinogenicity these should be considered more important tha[n] the non-fibrous cleavage fragments of tremolite and anthophyllite. (Ex. 410-23)

Dr. Arthur Langer, in his testimony, also discussed the difficulties in identifying these intermediate fibers. He stated that:

...some of us might call this a pyrobole, pyroxene and amphibole. This has also been described in various deposits, and you're going to ask me about the Vanderbilt talc deposit. That's fine because they're intergro[wthes] like this in the Vanderbilt talc deposit. These are the complex fibers that we have talked about that defy mineralogical classification. (Ex. Tr. 5/11, pp. 170)

The significance of "intermediate" or "transitional" fibers was also addressed by Dr. Langer, who stated that OSHA's major question should be "how common are they in the work place?" and answered "I don't think they're terribly common in the work place. They are only described in certain specific locales." (Tr. 5/11, p. 219).

OSHA notes that even those mineralogists who contend that asbestos is a separate mineral entity from non-asbestiform ATA, agree that intermediate forms exist. Dr. Tibor Zoltai, Professor of Geology at the University of Minnesota, explained that "...(T)he development of asbestiform properties is a gradual process, (and) depends on the extent of the appropriate conditions of crystallization. Consequently, there are variable qualities of asbestiform fibers. The poor quality asbestiform fibers of amphiboles are called byssolite, or brittle asbestos. The high quality asbestiform fibers, because of their highly developed flexibility, strength and physical - chemical durability, constitute desirable industrial materials and are exploited under the generic term of asbestos."(Ex. 546). Dr. Langer testified that based on Dr. Wylie's work, it is known that byssolite is not composed of unit fibrils. "So we would not classify byssolite as an asbestos mineral. Now some people consider this as a transition kind of mineral in characteristics."(Tr. 5/11 at 518) Other mineral forms exist which are intermediate between anthophyllite and talc, as discussed above.

In summary, the discussion indicates that populations of fibers and populations of cleavage

fragments can be distinguished from one another when viewed as a whole. For example one can look at the distribution of aspect ratios or even widths for a population of particles and can then generally identify that population of particles as being asbestiform or non-asbestiform. However when one looks at individual particles, (e.g. particles from air sampling filters) sometimes these mineralogical distinctions are not clear. Unfortunately the data in the record is insufficient at this time to precisely determine how often these situations occur.

The record also describes the presence of various kinds of "intermediate" fibers, which "defy mineralogic classification". Various participants have requested OSHA to base its regulatory decisions on precise mineralogic definitions. Clearly, any significant presence of mineral types which "defy classification", would defeat such an approach. Although these transitional fibers exist OSHA does not believe that independent evidence of their health effects exists which would support regulation. Dr. Langer testified that there are some fibers which "defy mineralogical identification" but they are a "small percentage" (Tr. 5/11, p. 230) Thus, although their presence lends credence to the explanation that asbestos minerals and non-asbestiform varieties developed on a continuum it does not change the fact that for most mineral deposits, asbestos and non-asbestiform habits are distinguishable.

OSHA finds, based on this record that while these intermediate fibers do exist, the record indicates that they are minor constituents of most mineral deposits. In general, when observed in their natural habit of growth, the two habits of asbestiform and non-asbestiform minerals are distinctly different. The record also indicates that populations of particles derived from mining, crushing or processing these minerals, are also distinctly different (e.g. in the distribution of widths and aspect ratios). However on an individual particle basis, which is often the case for particles from air monitoring samples, these distinctions may become less clear. The record indicates that there are situations where individual particles of asbestiform and non-asbestiform minerals may be indistinguishable. These situations are likely to be rare in occupational contexts but OSHA has little information upon which to make such a determination.

The regulatory implication of these findings are as follows: Several participants suggested that all forms of asbestos and their non-asbestiform analogues should be treated as a single mineral entity for purposes of regulation because the forms of ATA cannot be distinguished, and there is no clear mineralogic dividing line between various varieties of ATA. Dr. Charles Spooner, a witness for OSHA, a geochemist, a mineralogist and an industrial hygienist, in response to a question concerning how his laboratory distinguishes asbestos from fibers that are not asbestos, stated that "at this point if we identify the mineral tremolite, we make no distinction on the basis of fiber." (Tr. 5/8, p. 119). Dr. Spooner's post - hearing submission again noted that distinguishing asbestiform and non-asbestiform cannot be made reliably either on the basis of a hand sample or microscopic examination: hand - specimen characterization of mineral habit does not necessarily carry over to mineral habit on the micro scale; and, on the micro scale, high - aspect ratio cleavage fragments and asbestiform fragments can co-exist. Dr. Spooner recommended that "the issue must be resolved on the basis of biological activity and aspect ratio of the respirable fibrous bodies." (Ex. 512).

Dr. Bruce Case, in a letter to the British Journal of Industrial Medicine, November, 1990, provides a clear summary of the mineralogic argument for considering asbestiform ATA and non-equant non-asbestiform ATA to be a single substance for purposes of regulation:

The major flaw in the substitution of mineralogical definitions for microscopical

characteristics is a reliance of the former on gross morphology. For regulatory and health assessment purposes, it is microscopical morphology that counts: there is no evidence that potentially affected cells can distinguish between "asbestiform" and "non-asbestiform" fibers having equivalent dimensions. The lack of agreement as to what is and what is not"asbestiform" tremolite would be less critical if those who advocate such a definition could show that there is a clear line between the two forms when they present `fibrous' morphology. Unfortunately, this is not the case. Pooley has noted that the differences in structure between massive, acicular and fibrous morphology are not "sharply defined", but rather represent points on a continuum. So-called cleavage fragments may, in a strict morphological sense, be fibrous in their appearance in microscopic fields, and there is no convincing evidence that these `fibers' are of no public health concern. (Ex.529.4)

The ATS's report also concluded that mineralogic distinctions between different forms of anthophyllite, actinolite and tremolite were not clear: "It became apparent both from our review of the literature and from submissions made to this committee by experienced mineralogists, that the distinction between cleavage fragment and asbestiform fibers, although theoretically clear, is in practice extremely murky." (Ex. 525 at 3) As noted above, other participants took issue with these statements. In particular, in a post - hearing submission, the R.T. Vanderbilt Company directly took issue with the ATS statement quoted above as follows: "(a)t the OSHA hearing, Dr. Wylie, Dr. Langer and Mr. Addison explained that the distinctions at issue were in no way "murky" (theoretically, practically or otherwise). While we do not disagree that some gray areas exist (i.e., at the single crystal level), the important day - to day distinctions at issue in this rulemaking simply do not fit this "murky" characterization".(Ex. 529-6 at 3). Other presenters made similar statements.(See e.g. testimony of Dr. Wylie at Tr.5/9, at 103 and Dr. Lee at Tr. 5/9, at 1).

OSHA has determined that non-asbestiform ATA and asbestos anthophyllite, actinolite, and tremolite should be defined separately for regulatory purposes to conform to common mineralogic usage. As discussed above, the testimony of Dr. Wylie, Dr. Langer, Dr. Nolan, Dr. Campbell, the Bureau of Mines and others agreed that populations of asbestos and non-asbestiform ATA are separate mineral entities, which for the most part have widely diverging population characteristics which are the result of its habit of crystallization in nature. In addition, these characteristics, such as high fibrosity, fiber shape and size, and easy separability appear to be biologically relevant in producing disease. The agency notes the position it adopted in the 1986 standards, where it stated: "(t)he Agency recognizes that the minerals tremolite, actinolite and anthophyllite exist in different forms", and therefore required that warning signs and labels for ATA need not include the term "asbestos" (See 51 FR at 22679, 29 CFR 1910.1001 (j)(2)(iii), 1926.58(k)(1)(iii), recognized the mineralogic distinctions, but did not distinguish the minerals based on biologic effects. Thus, the difference between the Agency's 1986 and its current positions is not mineralogical and as explained above, is related to its view of the health effects evidence. Thus although the Agency now reaches a different conclusion than it did in 1986 concerning the evidence of health risks of non-asbestiform ATA, it continues to believe that the mineralogic forms are sufficiently distinctive to be treated differently for regulatory purposes. Also, unlike its determination in 1986, which was based on a far less extensive review of health effects evidence, the Agency now finds that differences in biologic effect between asbestos and its non-asbestiform analogues are likely related to the distinctions which define the two groups as separate mineral entities.

[57 FR 24310, June 8, 1992]

Regulations (Preambles to Final Rules)

V. Health Effects

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- **Record Type:** Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite
- **Section:** 5
- **Title:** V. Health Effects

V. Health Effects

In its proposal OSHA reviewed the available health effects evidence and preliminarily concluded that "there are a number of studies which raise serious questions about the potential health hazard from occupational exposures to non-asbestiform tremolite, anthophyllite and actinolite. However, the currently available evidence is not sufficiently adequate for OSHA to conclude that these mineral types pose a health risk similar in magnitude or type to asbestos. The Agency believes, however, that the evidence suggests the existence of a possible carcinogenic hazard and other impairing non-carcinogenic adverse health effects."(55 FR 4943).

After reviewing the rulemaking record compiled subsequent to the publication of the proposal, OSHA reaffirms its view of the health effects evidence. The few new studies that have come to light in this rulemaking are still inconclusive. It should be noted that OSHA believes the health effects evidence falls short regardless of whether this proceeding is viewed as deregulatory or as a regulatory initiative.

More specifically, OSHA believes that the evidence viewed as a whole does not rule out a possible carcinogenic effect of certain subpopulations of non-asbestiform ATA at an unspecified exposure level. However, as discussed below, various uncertainties in the data and a body of data showing no carcinogenic effect, do not allow the Agency to perform qualitative or quantitative risk assessments concerning occupational exposures. Further, the subpopulations of non-asbestiform ATA which, based on mechanistic and toxicological data, may be associated with a carcinogenic effect, do not appear to present an occupational risk. Their presence in the workplace is not apparent from the record evidence.

1. Human Studies

Summary

The epidemiologic studies submitted to this record consisted of no studies which were not available to OSHA at the time of the proposal. The interpretations submitted in comment and testimony also reiterated positions taken prior to the proposal, although participants expanded on them. Additional analyses concerning reported cases of cancer in the NIOSH

study cohort were submitted, both in support of the position that the talc exposure was correlated to cancer, and in support of the opposing view that smoking was a likely cause of any elevated SMR.

A review of the human studies in the record follows: Where no new interpretative comment was offered, only a summary describes it. Where new comment or updated data was submitted, a discussion is presented. The discussion is organized around the categorization of the minerals to which the cohorts were exposed. As discussed at length in the proposal, uncertainty about the content of the mineral exposure at times made definitive interpretation difficult. However, because the substances to which workers are exposed are mixed, OSHA believes that mixtures can be evaluated in their own right. If disease cannot be correlated to exposure to a specific mineral in a mixed mineral product, then prudent health policy allows OSHA to ascribe causation to the mineral mixture, rather than to any component.

a. Studies of exposures to ATA and asbestos contaminated ores.

As OSHA noted in its proposal, McDonald et al (Ex. 410-6) reported an excess of respiratory cancer including mesotheliomas, among vermiculite miners in Libby, Montana. Vermiculite, a mica - like mineral ore, was contaminated with four to six percent tremolite-actinolite fibers. Mineralogic analysis of the Libby mine's ore showed the fibers to be mostly an asbestiform type of fiber. However there were also "massive amphibole crystals, which when pulverized produced cleavage fragments resembling fibers"(p.439). OSHA noted, "[a] lthough the fiber analyses indicate that some of the particles were non-asbestiform in origin, the predominant fiber exposure appears to be from asbestiform tremolite. ...Standardized Mortality Ratios(SMRs) were computed for the cohort of 406 Men. When compared to death rates of men in the U.S., there was a substantial excess number of deaths from respiratory cancer (SMR=245). Four of the 43 deaths were from mesothelioma. There was also a substantial excess number of deaths from non-malignant respiratory disease(SMR=255). There was no excess number of deaths from cancers of non-respiratory sites. When compared to the death rates of Montana men, the cohort's excess mortality was even greater; for example the SMR for respiratory cancer rose from 245 to 303." OSHA stated in the proposal that the result of the Libby, Montana study and other studies of workers exposed to tremolite asbestos contaminated ores "provide additional evidence on the high potency of asbestiform tremolite. Although non-asbestiform tremolite was present it is not possible, from the data presented, to discern what contributing effect the non-asbestiform minerals may have had."(55 FR 4944).

Most comment and testimony during the rulemaking concerning the Libby Montana study reiterated OSHA's earlier analysis. The American Thoracic Society pointed out that the mineralogic characterization of the Libby deposit as containing tremolite asbestos has been challenged, and for that reason and because this is a "non-replicated" study, warned against relying on it.(Ex. 525, p. 5) Dr. Nicholson, in his testimony, pointed out that the presence of non-asbestiform minerals in the deposit, made the study compatible with the risk expected on the basis of measured fiber concentrations (Tr. 5/8, p. 55). NSA noted that "the Libby vermiculite workers were exposed to asbestiform tremolite and asbestiform actinolite and thus this study is not useful in the examination of the non-asbestiform ATA question." (Ex. 524, p. 26.) As stated in the preamble to the proposal, OSHA believes that the results of the Libby, Montana study, and other studies where miners were exposed to both asbestos tremolite and non-asbestiform tremolite (see e.g. Kleinfeld et al, Ex. 84-402 and Brown et al (Ex. 84-25) provide additional evidence on the high potency of asbestiform tremolite. Although non-asbestiform tremolite was present it is not possible from the data presented, to

discern what contributing effect the non-asbestiform minerals may have had to the excess cancer observed in this study.

b. Studies of exposures to mixtures of other non-asbestiform analogues with non-asbestos minerals.

The Homestake gold mine study (Ex. 84-45, Docket H-033c) was a retrospective cohort mortality study of 3328 gold miners who worked in full-time underground jobs for at least one year between 1940 and 1965. There were 861 observed versus 765 expected deaths overall. The primary exposures were to amphibole minerals in the cummingtonite-grunerite series (the non-asbestiform analogue of amosite) and silica. According to the study's investigators "no association, as measured by length of employment underground, dose (total dust x time), or latency was apparent with lung cancer mortality (43 observed vs. 43 expected). However Dr. Nicholson noted that the conclusion of no excess lung cancer risks associated with exposures at the mine was based on calculations using U.S. mortality rates, rather than South Dakota mortality rates. Had South Dakota mortality rates been used, SMRs would have been raised to 160, rather than the 100 reported by the investigators.(Tr. 5/8, p. 81-2). Dr. Bob Reger who testified for the American Mining Congress (AMC) suggested that such an adjustment is improperly made without adjusting for age (See Tr. 5/8, p. 82). Although OSHA believes that uncertainty in interpretation is introduced by the study's use of U.S. mortality rates, reconstruction of the SMRs applying the South Dakota mortality rate is hindered by the lack of data which would allow an age specific reconstruction. Dr. Nicholson also noted that the Homestake results were not incompatible with an asbestos effect, because in the longer duration category there is a total of only three deaths, an additional uncertainty, and there is a possibility that one has individuals that are survivors and "...demonstrate a lower risk by virtue of the fact that they could have had lesser exposure jobs, and, thus, be at lesser risk ..."(Tr. 5/9, p. 83). OSHA believes Dr. Nicholson's comments correctly state some of uncertainties of the study, i.e., small number of deaths, and the possibility that retirees can be a survivor population. These uncertainties do not, by themselves, provide a basis for interpreting the Homestake studies as confirming evidence for the carcinogenic effect of non-asbestiform minerals. The study is not inconsistent with a positive association and does not prove that there is no association. However, it can also not be interpreted as clear evidence of association.

Other studies concerned two groups of iron ore miners and processors, who were exposed to taconite dust which may have contained cleavage fibers of the cummingtonite-grunerite series (Higgins et al., 1983 (Ex. 410-18): Cooper et al., 1988 (Ex. 427)). OSHA agrees with the analysis of all participants who commented on these studies, to the effect that they do not inform as to the carcinogenicity of non-asbestiform ATA, perhaps because of the low exposures in one mine and the lack of latency to observe lung cancer in the other (See e.g. NSA's post hearing brief (Ex. 524 p.27), Dr. Nicholson's testimony (Tr. 5/8, pp. 55-56)).

In its proposal OSHA described at considerable length the studies of the New York State tremolitic talc miners and millers, which had been undertaken by NIOSH. The entire preamble discussion is incorporated here (see 55 FR 4946). One significant interpretive issue concerns the mineral content of the deposit and thus the employees exposures. Vanderbilt testified that "the ore composition is fairly consistent...the content of the talc being between 20 to 40 percent, serpentine, 20 to 30 percent; the tremolite 40 to 60 percent, the anthophyllite between zero and five (percent), and ...quartz...in very trace amounts." (Tr. 5/11, p.103). Testimony in the record supports Vanderbilt's claim that any of the asbestos minerals that falls into the scope of this standard is not a component of the ore. (See Langer

et al, and Dunn GeoScience in the prehearing submission of the American Mining Congress and the NSA, Ex. 479-6, 479-23; R.J. Lee in the Vanderbilt Dust Project, Ex. 433). While the reports of these analysts find no evidence of the six asbestos types in the Vanderbilt talc mines, all three noted the presence of asbestiform talc fibers and "transitional particles". These are the same "transitional particles", described earlier in the section on Mineralogic Considerations, which resemble asbestos and talc but are not technically asbestos. NIOSH reiterated its original evaluation that the Vanderbilt deposits contained asbestiform as well as non-asbestiform tremolite and anthophyllite. (See Tr. 5/9, p. 11.) OSHA notes that the debate over the mineralogic content of the Vanderbilt mines remains unresolved. OSHA believes however that the presence of asbestiform talc and the so called "transitional particles" together with the undisputed presence of non-asbestiform tremolite and anthophyllite may have led to the identification of various particles as asbestiform tremolite and/or anthophyllite.

Various industry and government sponsored reviews and updates of NIOSH's study have been conducted. In the NPRM, OSHA concluded that "the NIOSH studies provide evidence to support the possibility that exposure to minerals at the mine is correlated to the excess mortality from lung cancer and nonmalignant respiratory disease and an excess of pleural thickening and lung decrements. However due to uncertainties in the mineral content and mixed mineral contents, the study does not show that it is more likely than not that non-asbestiform fibers are the cause of the disease."(55 FR 4947).

A former NIOSH researcher, Dr. John Gamble, who has criticized basing the regulation of ATA as asbestos on the NIOSH study, submitted additional material to substantiate his contention that attributing excess cancer to non-asbestiform ATA was speculative (Ex. 478-8). Gamble performed an update and re-evaluation of the 1980 NIOSH study in which he added eight more years of follow-up, an exposure latency analysis, and a nested case-control study to control for smoking and other occupational exposures. In his analysis Gamble found a significant increase in mortality for all cause (SMR=128), all respiratory diseases (SMR=251), all malignant neoplasms (SMR=145), and lung cancer (SMR=207). The lung cancer SMRs were elevated in the 20-36 year latency group (SMR=258) and for workers with less than one year tenure at the mine (SMR=357). In the nested case-control study Gamble found no apparent increased risk associated with non-Vanderbilt jobs. However he did find that the odds ratio for cases who smoked was six times that of combined ex-smokers and nonsmokers. Gamble stated in his conclusions that "Although lung cancer SMRs are elevated, we could not find an exposure-response relationship. The lack of an increase risk of lung cancer is consistent with other mining populations exposed to non-asbestiform minerals. The time occurrence of lung cancer is consistent with a smoking etiology." (Ex. 478-8, p.2) NIOSH has stated that Dr. Gamble's opinions "are his alone; arise from activities he performed which, in part, created the appearance of a conflict of interest; and represent conclusions, as judged by independent reviewers, which are not supported by data."(Ex. 520, p. 3). NIOSH continues to support the findings of it earlier studies in the New York talc mines, which, they concluded, provide clear evidence of an increase in lung cancer and other asbestos related disease in talc workers. (Ex. 478-15, Tr. May 8, p. 24) In its post hearing comments NIOSH submitted an update of the Gouverneur Talc study which added eight new lung cancers to the ten identified in the earlier report (Ex. 532). According to NIOSH the SMR for lung cancer was uniform across tenure strata and increased with increasing latency. There was a statistically significant excess in lung cancer in those with 20 years of more latency and with less than one year employment. Those in this latency group with greater than one year duration also exhibited an increased risk but it was not statistically significant. The increased risk of lung cancer among those with short duration also was observed in the

1989 analysis. (Ex. 532 at p.5). NIOSH offered three explanations: cohort members may have been employed in other New York State talc mines and mills where there may have been additional exposures to the same or to similar types of mineral dust and noted that it is known that half of the lung cancer cases worked on other talc mining operations; some of the short duration group may have had very high exposures; and smoking habits among the employees may have been different from the reference population. However, NIOSH performed an exercise to show that differences in smoking could not account for the observed increase in lung cancer. NIOSH calculated SMRs assuming that 100 percent of the cohort were smokers. NIOSH noted that the SMR for lung cancer would have been only 160, instead of 207. In addition, the updated results show the SMR for non-malignant respiratory disease was significantly elevated among those with more than one year of tenure(SMR=290, CI 144, 518). The types of nonmalignant disease observed in this study is not known to be smoking related.

OSHA notes, however, that virtually no other participant endorses the NIOSH study as a basis for regulation. For example, the ATS report noted that the results of the case-control study and the lack of any dose-response relationship for lung cancer risk in the cohort study do not support a conclusion that the elevated risk in this population was attributable to mine exposures.(Ex. 525, p. 6) Dr. Richard Morgan, testifying for the NSA, stated that "Even if subsequent studies of the Vanderbilt mine permit a conclusion that an occupational exposure at the mine contribute to the risk, there will remain the problem of deciding which exposures (among many) are likely responsible. At this time, however, there is no evidence from these studies that will permit any conclusion concerning non-asbestiform ATA." (Ex. 490C, p. 180).

In summary, OSHA believes that the epidemiological studies, as a whole, provide insufficient evidence to inform as to the carcinogenicity of non-asbestiform ATA. For example, epidemiological studies involving exposures to non-asbestiform amphiboles other than non-asbestiform ATA are hindered by low "fiber" counts and short latency periods. It is likely that even if exposures had been to "true" asbestos, a positive response would not have been observed under similar low dose, low latency conditions. Epidemiological studies of upstate New York talc miners are hindered by the fact that workers were exposed to a mixture of minerals (the identification of which is still somewhat at debate). Although plausible arguments have been presented that suggest that the increase in lung cancer is consistent with a smoking etiology, OSHA believes that it is also likely that exposures at the mine are responsible for the observed disease, especially in the case of nonmalignant respiratory disease. Nevertheless, due to the mixed mineral exposures OSHA concludes that it is not possible from the present data, to determine what role the non-asbestiform ATA may have played in the induction of that disease.

2. Lung Burden Studies

In the proposal OSHA discussed the findings of several lung burden studies. One study discussed the case study of a mesothelioma death in which an analysis of the autopsied lungs showed elevated levels of tremolite (Ex. 410-10). The fibers of tremolite were of low aspect ratio (i.e. 7:1) and OSHA concluded that low aspect ratio tremolite appeared to have contributed to the induction of mesothelioma (55 FR 4944). However, Mr. Kelly Bailey, testifying for the NSA, took issue with OSHA's conclusion noting that this study involved only a single case study of an individual who was also exposed to chrysotile and the authors of the report stated that the possible effects of tremolite are uncertain. Mr. Bailey also noted that the tremolite "present in the lungs of this case had a mean aspect ratio of 7:1" and "... it

is obvious that a distribution of asbestos fibers were found, many with aspect ratios greater than 20:1" (Bailey testimony, Ex. 479-23).

In the proposal OSHA also discussed lung burden studies among miners exposed to both chrysotile and tremolite (Rowlands et al., Ex. 84-178; McDonald et al., Ex. 84-175; Glyseth Ex. 312). These studies indicated that despite high exposure levels of chrysotile, analyses of autopsied lungs showed higher lung burdens of tremolite. OSHA concluded however that the fact that there were was a mixture of mineral fiber types precluded one from ascribing causation to one particular mineral type.

The American Thoracic Society (ATS) reviewing the same studies concluded that "although the role of chrysotile versus tremolite in producing disease in these patients could not be clearly sorted out, the ...data appear to indicate that fairly low aspect ratio fibers of tremolite are capable of causing disease, probably in fairly low concentrations in the case of pleural plaques, but certainly only in very high concentrations in regard to mesothelioma and asbestosis" (Ex. 525, p. 10).

In response to the ATS report, Dr. Arthur Langer, a mineralogist, noted that the "fairly low aspect ratio fibers of tremolite" referred to in the ATS report involve fibers measurements made counting all fibers (i.e. not only those greater than 5 micrometers) and using geometric means. Langer states that "geometric means can be very misleading and the raw data are needed. If one only counts the fibers longer than the 5 um geometric mean, the aspect ratio of the tremolite fibers is greater than 20:1." Dr. Langer adds that "the data from Canada are problematic in that there is a mixed population of tremolite (when present) which skews size distribution in lung burden studies towards short wide `fibers'. The disease (plaques) may have been caused by thin fibers (asbestos) at the pleura. The thick cleavage fragments in the lung parenchyma may have little to do with the disease process at the pleura" (Ex. 529-7, pp. 15-17).

Lung burden analyses were also performed by Dr. Jerrold Abraham, a physician and pathologist at the State University of New York. In his testimony and written comments to the proposal, Dr. Abraham presented his analyses of the lung tissues of deceased talc miners from upstate New York. Dr. Abraham testified that these analyses showed that the lungs of these talc miners included both asbestos and non-asbestiform minerals, despite the fact that the talc miners are claimed by some parties to be exposed to only non-asbestiform tremolite. (Tr. May 10. p. 119).

However several hearing participants objected to Dr. Abraham's analyses (See Morgan and Reger for the American Mining Congress, Ex. 508; Langer et al., Ex. 511; and the R.T. Vanderbilt Co., Ex. 513). In summary, these commentors stated that the review and analyses of the talc miner cases lacked documentation and included neither smoking histories nor prior occupational exposures. They suggested that these cases may have had heavy smoking histories or prior exposure to asbestos which could have induced the observed disease. In particular Dr. Langer, a mineralogist, stated that the "limitations of the report are so great that the data are reduced to anecdotal observations" (Ex. 511).

OSHA acknowledges the limitation of these analyses. However, the finding of a rare disease such as mesothelioma, among a group of miners exposed to mixed mineral environments, raises concern over these type of exposures. Furthermore smoking is not known to induce mesothelioma. However, as was stated in the case of the Canadian chrysotile miners, the mixture of mineral types precludes one from ascribing causation to non-asbestiform minerals.

This problem, in addition to the uncertainties involved in Dr. Abraham's analyses, do not provide sufficient information to conclude that non-asbestiform ATA present a risk similar in magnitude or type to asbestos.

In summary, lung burden analyses indicate that non-asbestiform minerals are present in the lungs of cases diagnosed with lung cancer and mesothelioma. Several arguments have been put forth by hearing participants both for and against the implication that non-asbestiform contributed to the observed disease. OSHA believes that it is difficult to discern what contributing effect the non-asbestiform minerals may have had because other asbestiform minerals are also present.

3. Animal Studies

a. Mechanistic studies

OSHA noted in the proposal that several studies in the record suggested that fiber dimension is an important factor in asbestos-related disease development. (55 FR at 4944). Dr. Merle Stanton's landmark study (Stanton et al.(Ex. 84-195, Docket H-033c)) is generally accepted as showing that fiber dimension is an important determinant in mesothelioma production. Dr. William Nicholson, testifying for OSHA described Stanton's study in his testimony. "Seventy-two separate experiments were conducted with different mineral materials, including the commercial asbestos varieties, man-made mineral fibers and minerals containing varying other percentages of fibers. The results of those studies indicated, and his major conclusion was, that the length and diameter of the fibers were the most important factors determining carcinogenicity. Longer fibers were more carcinogenic than shorter ones, and thinner ones more so than thicker ones..." (Tr. 5/8, p. 40).

Most comment and testimony acknowledged that Stanton's work demonstrated that fiber dimension is generally related to tumor production. (See e.g. NSA's post-hearing brief at 19, Ex. 524; Dr. Oehlert's testimony Tr. 5/9, p. 88) For example, Dr. Oehlert, a statistician testifying for NSA stated "In agreement with Stanton, I find that the log number of index particles per microgram in a sample is the best single predictor of tumor probability for that sample. The index particles -- I believe the term was coined by Stanton -- are those particles longer than 8 micrometers and narrower than .25 micrometers."(Tr. 5/9, p. 88).

However, participants disagreed over more specific interpretations of Stanton's study. For example Dr.Nicholson (Ex. 484, Tr. 5/8), NIOSH (Ex. 478-15, Tr. 5/9), and Dr. Groth (Tr. 5/10) asserted that Stanton's work showed that all fibers with certain dimensions had tumorigenic potential; that the greatest correlation existed between fibers of a diameter less than .25 micrometers and greater than 8 micrometers (the "index particles"), but that even a size dimension of 4 to 8 micrometers in length, with a diameter of .25 to 1.5 micrometers had a correlation coefficient of .45. (See e.g. testimony of Dr. Nicholson, 5/8 at 41).

The NSA, in its cross-examination and post-hearing submissions, challenged the interpretation that Stanton's studies show that fibers with aspect ratios as low as 3:1 or 5:1 increase tumor response stating:

During the hearing testimony, the fact that all of the studies involved exposures to a population of fibers or particulates was consistently agreed upon. This fact does not allow one to attribute a specific aspect ratio or dimension as the cause of a response in these animal

studies... It is important to recognize that the entire particle size profile of the exposure (width, length, and aspect ratio distribution) contributes to the results of any study. When one looks at the particle width, length, and aspect ratio distributions of cleavage fragments and compares these same distributions to those for asbestos, the population characteristics are easily seen to be quite different...(NSA, post-hearing brief, Ex. 524 at 16).

Various statistical analyses of Stanton's studies were submitted. The study cited as supporting low aspect ratio toxicity, is Bertrand and Pezerat (Ex. 84-114, Docket H-033c)). OSHA described this study in its proposal as finding "a high correlation between aspect ratio and tumor probability for durable minerals. In their analysis tumor probability began to rise at aspect ratios of about 3 to 5".(55 FR at 4944). However, the Bureau of Mines stated in their comments that OSHA did not fully describe Bertrand and Pezerat's findings. They pointed out that "the slope of the curve was extremely small at 3:1 to 5:1 aspect ratios and aspect ratios of 3:1 to 5:1 represent about 5 percent probability (base level in the study)" and " No indication was given as to whether 5 percent is statistically significant to control populations." (Ex. 478-6) Similarly the NSA stated that since Bertrand and Pezerat's "analyses deal with distributions of aspect ratios, it is inappropriate to suggest that an aspect ratio of three or five or any specific value is the reason for the carcinogenic response". (Ex. 524, p. 22) NSA's witness, Dr. Gary Oehlert presented a statistical reanalysis of Stanton's data. Dr. Oehlert stated that his analysis showed that the log number of index particles was the most significant predictor of tumor probability and once index particles have been accounted for, aspect ratio has no further predictive information to provide. (Tr. 5/9, p. 90). However, it should also be noted that although Dr. Oehlert concluded that the number of index particles is the "best" predictor of tumor probability, his analyses also show that aspect ratio is statistically significantly correlated to tumor probability. Dr. Oehlert suggested that this correlation is likely due to the fact that aspect ratio is related to the number of index particles. Nevertheless he states that nonindex particles may contribute to carcinogenicity, but that the Stanton data are not precise enough to determine their influence. In addition, Dr. Oehlert noted that the mineral type is a significant predictor of tumor probability... and should be included when estimating tumor risk.(Tr. 5/9 at 2-87).

Dr. David Groth, a pathologist, testifying on his own, concluded from his review of Stanton's work that "the results of these studies (i.e. Stanton's) clearly document the importance of fiber size and the induction of cancer by fibers. They also indicate that the chemistry and crystalline structure of the fibers play either no role or a secondary role in the induction of cancer by fibers." Dr. Groth stated that "the results of these experiments have not been seriously challenged by data derived from other animal experiments, and remain as valid today as they were in 1981"(Tr. 5/10, pp. 30-31).

Other dimensional hypotheses were also submitted to the record. Dr. Morton Lippman's 1988 paper which, after reviewing various human and animal studies, identified dimensional ranges for different health effects, was submitted by NIOSH (Ex. 478-15) and others (NSA, Ex. 479-23; AMC, Ex. 479-6). Based on his review of animal injection studies and human lung analyses, Dr. Lippman concluded that the various hazards associated with asbestos (i.e. asbestosis, mesothelioma and lung cancer), are associated with critical fiber dimensions and these dimensions are different for each disease. For example, Dr. Lippman concluded that asbestosis is most closely associated with the surface area of fibers with lengths greater than 2 micrometers (um) and widths greater than 0.15 um; mesothelioma is most closely associated with the number of fibers with lengths greater than 5 um and widths less than 0.1 um; and lung cancer is most closely associated with the number of fibers with lengths greater than 10 um and widths greater than 0.15 um.

The data in the record support and OSHA concludes that fiber dimension is certainly a significant determinant of biological function. OSHA also concludes that despite the various re-analyses of the Stanton study, the basic premise of this study still holds true, that is, that tumor probability increases with the number of long and thin durable particles. However the data available are not precise enough to determine at what point there is no significant carcinogenic potential.

OSHA further concludes that longer, thinner fibers are likely to be more pathogenic. The evidence shows that dusts containing cleavage fragments, rather than asbestiform material, contain substantially fewer longer thinner particles. Thus, a dimensional theory of pathogenicity does not by itself demonstrate that non-asbestiform ATA has similar health effects to asbestos. Even if dimension were the principal determinant of biologic potential for mineral dusts, the evidence in this record is not sufficient to allow OSHA to draw the line for regulation for non-asbestiform ATA at specific dimensions.

b. Empirical Studies

OSHA stated in the proposal that the empirical studies in animals are not sufficiently supportive of the mechanistic information to conclude that the risks are similar in magnitude and type for both asbestiform and non-asbestiform minerals.(55 FR at 4946). Although OSHA discussed a preliminary report of early results in its proposal, the one totally new study submitted to the record concerned intraperitoneal injection studies in rats of six samples of tremolite of different morphological types conducted by a Scottish team consisting of John Davis, John Addison and others. Dr. Addison testified at the hearing and submitted both draft and final papers describing the experiment (Ex. 479-22; Tr. 5/11). In this study six different samples of tremolite of different morphological types were prepared as dusts of respirable size and used in intraperitoneal injection studies in rats. Three samples were identified as being tremolite asbestos (California, Korean and Swansea samples). A fourth sample, called Italian tremolite, was initially identified to be non-asbestiform but was later identified, after the tumors were observed, as a "brittle type of fibrous tremolite". The two remaining samples were identified as non-asbestiform tremolite (Dornie and Shinness samples). The three asbestiform tremolite samples produced mesotheliomas in almost all animals tested (California, 100 percent; Swansea, 97 percent; and Korean, 97 percent). The Italian sample which had "relatively few asbestos fibers" produced mesotheliomas in 67 percent of the animals tested although at significantly longer induction periods. The two remaining samples produced "relatively few tumors" (Dornie, 12 percent and Shinness 5 percent) and were considered, by Dr. Addison to be within the range of background incidence of mesotheliomas observed in historical controls in his lab.

Table 1. Summary of survival data and fiber number for 10 mg dose

Sample	#animals	#mesoth-eliomas (percent)	Median survival time (days)	# fibers (10(5))/mg	#fibers (10(5))/mg len> 8 um dia.< .25
Calif.......	36	36 (100)	301	13430	121
Swansea.....	36	35 (97)	365	2104	8
Korea.......	33	32 (97)	428	7791	48
Italian.....	36	24 (67)	755	1293	1
Dornie......	33	4 (12)	*	899	0
Shinness....	36	2 (5)	*	383	0

* Not calculated, table extracted from Davis et al. (Ex. 479-22)

From these results Dr. Addison concluded that all the samples possessed some potential to produce mesotheliomas. However he pointed out two apparent anomalies. One, the Swansea sample had fewer fibers than the Korean sample but both produced a maximum response. Dr. Addison explained that one possible explanation may be that the relationship between fiber number and mesothelioma production is blurred by the overdose situation (i.e. a saturation effect). The second anomaly noted by Addison was the difference in fiber number and mesothelioma production between the Italian and Dornie samples. From Table 1 above, as presented in the Addison study, the Italian sample had 1293 x 105 fibers/mg and the Dornie had 899 x 105 fibers/mg. Dr. Addison notes however that when only those fibers from this group (i.e. fibers with aspect ratios > 3:1) which have lengths greater than 8 um are counted, the Italian sample had 1/3 fewer fibers but produced a higher percentage of tumors (See for example Tables 2(d) and 2(e), Ex. 470-22). Addison also states that while "it is true that many of the long fibers in the Dornie specimen were greater than 1 um in diameter...if only fibers greater than 8 um in length and less than 0.5 um in diameter were considered, the two specimens have approximately equal numbers which still does not conform to their very different carcinogenic potential." (Ex. 479-22, p 13).

This study was interpreted differently by various participants. The NSA and National Aggregates Association's joint submission found the results of the Davis et al study consistent with its position that "the higher the proportion of tremolite federal fibers (i.e. particles with aspect ratios > 3:1) with widths less than 0.5 um, the greater the incidence of tumors. Conversely, the higher the proportion of tremolite federal fibers with widths greater than 1 um, the lower the incidence of tumors."(Ex. 529-8, p. 3). The NSA in its post hearing comments further stated that the Davis et al data "showed an absence of excess tumors from non-asbestiform ATA, and that the best parameter to explain the formation of tumors was the number of >32:1 aspect ratio Stanton particles, not 3:1 cleavage fragments." (Ex. 524, p.2) NIOSH found that the Davis et al study showed that all forms of tremolite asbestos should be considered carcinogenic, and that it presents no clear evidence indicating that non-asbestiform tremolite is not carcinogenic. However NIOSH expressed serious concerns about the protocol and presentation of the study as follows: lack of controls or historic incidence data for the strain of rat used; unclear mineralogic classification of various samples, particularly numbers 4, 5 and 6; the small number of fiber and particle counts obtained for each sample may limit the accuracy of the size distributions reported; lack of knowledge concerning the representativeness of the non-asbestiform varieties used, and because of saturation doses causing maximal responses for three samples, dose-response relationships cannot be developed for these samples. NIOSH cautioned that because the study has been neither peer reviewed nor published, lacks controls, and has other defects, it should not be relied upon by OSHA for any significant regulatory decision. (Ex. 532) Langer et al took issue with most of the NIOSH criticisms in their post hearing comments (Ex. 550). In particular they state that NIOSH is incorrect in its statement that the mineralogic classification of samples 4, 5 and 6 is unclear. Langer et al point out that the minerals were characterized by "continuous scanning X-ray diffraction, polarized light microscopy as well as scanning and transmission electron microscopy equipped with an energy dispersive X-ray spectrometer." They also disagree with NIOSH statements that "the small number of fiber and particle counts obtained for each sample may limit the accuracy of the size distribution reported." Langer et al note that "in each operation 300 fibers of all sizes were counted and measured..". and " to improve the statistical quality for long fibers the count was continued only for fibers >5 um... until 100 fibers > 5 um had been counted...this was done twice for

most of the samples and three times for the Ala di Stura (i.e. Italian) and Dornie samples" (Ex. 550, p. 7).

Dr. David Groth, a former NIOSH scientist, testifying on his own behalf, disagreed with statements made by Addison that the tumor incidence observed for the Dornie sample (12 percent) and the Shinness sample (5 percent) was within the background incidence for historical controls. Dr. Groth contends that this observation is not supported by the data published from Addison's lab. Dr. Groth states that "In two separate publications in 1986..using the same strain of rats (AF/HAN) in full life-span experiments no mesotheliomas were observed in 61 control rats in one experiment and 64 control rats in another experiment." (Ex. 529-1, p.2) In addition Dr. Groth cites several other results from Addison's lab which show no background incidence of mesothelioma for this strain of rat. Dr. Groth concludes the "the finding of peritoneal mesotheliomas in 6 percent of rats injected with the Shinness tremolite sample is a significant finding and provides further support for Stanton's theory regarding the carcinogenic potential of all fibers, including non-asbestiform fibers." (Ex. 529-2, p. 3).

According to Dr. Addison, a co-author of the study, "the results of the...study suggest that a wide ranging group of tremolite samples all possessed some potential to produce mesotheliomas following injection into the rat peritoneal cavity" and "In general carcinogenicity relates to the number of long thin fibers than to any of the other dimensional characteristics of the dusts that were considered but the relationship was by no means exact."(Ex. 479-22, p. 13). Dr. Addison added however that "the intraperitoneal injection test is, however, extremely sensitive and it is usually considered that, with a 10 mg dose, any dust which produces tumours in less than 10 percent of the experimental group is unlikely to show evidence of carcinogenicity following dust administration by the more natural route of inhalation". (Ex. 479-22, p. 14-15) He thus concluded that human exposure to such a material "will certainly produce no hazard."

Based on the record evidence, OSHA believes that the Davis et. al study confirms the view that various forms of tremolite have different pathogenic potential. For five of the six samples, constant relationships prevailed between asbestiform fibers and high potency and between non-asbestiform dusts and low potency. Interpreting the Italian sample is more problematic, and only speculative explanations exist for why it is more potent than would have been predicted based on its relatively small number of high aspect ratio fibers.

Other animal studies were the subject of testimony and comment, but the analyses essentially reiterated positions taken by the parties in communications to the Agency prior to the proposal. OSHA described the Smith study in its proposal as follows: "Smith et al injected four different talc samples intrapleurally into hamsters. The samples included fibrous tremolitic talc from New York State, tremolitic talc from the facility studied by NIOSH, tremolitic talc from the Western U.S. and asbestiform tremolite. Only the western talc and the asbestiform tremolite induced tumors in hamsters."(55 FR 4948).

Various mineralogic characterizations of the western talc have been made. Dr. Wylie, in cross-examination, reiterated her earlier characterization of the western talc, as a fibrous form of tremolite. Dr. Wylie further explained "it wasn't obviously only a sample of asbestos. I think I referred to it as byssolite." However because evidence of that sample consists of one photograph of that material, Dr. Wylie cautioned against drawing "too many conclusions ...about that one sample." (Tr. 5/9, p. 235.) OSHA agrees with Dr. Wylie and additionally notes that other deficiencies make the Smith study inconclusive. (See discussion

in the preamble to the proposal, where OSHA noted the small number of animals, early death of many animals, lack of systematic characterization of fiber size and aspect ratio; 55 FR 4948).

The few additional animal studies undertaken to examine the toxicity of non-asbestiform ATA, either do not inform or do not show equivalent toxicity of ATA. The 1974 intraperitoneal injection rat study conducted by Pott et al, showed no tumor development for the animals injected with the primarily non-asbestiform actinolite sample (Ex. 479-6). The Cook studies of ferroactinolite fibers, show that the sample which was observed to undergo a higher degree of in vivo longitudinal splitting, resulted in more retained fibers, and in a higher concentration of retained fibers. Dr. Wylie noted that "(t)he durability of amphiboles in vivo is well known and the only way for this sample to break down into fibers of smaller widths is for separation of the fiber bundles to have occurred in vivo. They don't dissolve. Fiber bundles are the hallmark of asbestos and this characteristic is clearly revealed in the behavior of Coffin's ferroactinolite". (Tr. 5/9 at 104). Additional evidence was submitted in support of the view that the ferroactinolite sample was, in significant part, asbestiform. Thus, Dr. Lee concluded, based on his electron microscopic analysis, that as much as 61 percent of the sample may be asbestos with 33 percent existing as bundles (Ex. 490F Attach. A, p.2). OSHA concludes that it is more likely that the ferroactinolite sample that resulted in excess tumors is asbestiform and for that reason, the experimental results are not informative concerning the biological potential of non-asbestiform ATA.

OSHA believes that as a whole the animal experiments conducted confirm that for clearly differentiated dust populations, qualitative differences in carcinogenic potential exist between what is commonly considered "asbestos" and "cleavage fragments". Virtually all participants in this rulemaking agreed with this assessment. Even participants who endorsed regulation of non-asbestiform ATA as asbestos agreed that the longer, thinner fibers were more potent. (See Nicholson at Tr. 5/8, p. 60).

c. Conclusions

Based on the rulemaking record before it, OSHA reaffirms its preliminary determination in the proposal that there is insufficient evidence to conclude that non-asbestiform ATA present a health risk similar in kind and magnitude to that of their asbestiform counterparts.

Asbestos is regulated as a carcinogen. Some health effects data relating to non-asbestiform ATA involved exposures to mixed mineral populations or particles which were poorly characterized such that no conclusions could be made regarding the carcinogenicity of non-asbestiform ATA. In other cases there were health effects data in humans, reportedly exposed to non-asbestiform ATA, which did not show excess cancer risks similar to those observed among animals and humans exposed to asbestos. However some of these data suffer from methodological deficiencies (e.g. low fiber exposure, poor animal survival and poor mineralogical characterization). These flaws may limit the studies' ability to detect the carcinogenic potential of non-asbestiform ATA if one is present. However, in many of the studies, asbestiform and non-asbestiform minerals were tested in the same experiment using the same protocol and only the asbestiform minerals induced a positive response. Thus, while the studies' results cannot be used to show that non-asbestiform ATA presents no carcinogenic risk, due to certain methodological flaws, the results from these studies do suggest that if a carcinogenic risk does exist for non-asbestiform ATA, the risk is likely to be substantially less than that of asbestos. Given both the lower potency of any potential carcinogenic risk, and the high degree of uncertainty that would accompany any such

estimate, OSHA believes the health effects evidence does not support treating non-asbestiform ATA as presenting a risk equivalent in kind or extent to asbestos.

In addition, OSHA finds that the evidence is insufficient to conclude that exposure to non-asbestiform ATA may result in a significant risk of nonmalignant respiratory disease (NMRD). Unquestionably, exposure to historic levels of tremolitic talc carried with it a significant risk of NMRD (i.e. pneumoconiosis). For example, studies by NIOSH, of tremolitic talc miners and millers in upstate New York (Ex. 84-181, Docket H-033c) have shown an excess risk for NMRD (SMR=280), among exposed workers. Similar findings of excess NMRD have also been observed in updated studies of this same group of workers both by NIOSH (SMR=250) and Gamble et al (SMR=251) (Exs. 532 and 478-8). Moreover NIOSH concluded in their update, that the observed excess in NMRD is more consistently associated with exposures at the mine. NIOSH's conclusion is based on their observation that a larger excess risk is observed among those employees with greater than one year employment at the mine (SMR=289) compared to those employees with less than one year employment at the mine (SMR=194). Even officials at the mine acknowledge the NMRD risk associated with the tremolitic talc. For example, in his testimony at the hearings, John Kelse, an industrial hygienist for the R.T. Vanderbilt Company, stated that "(t)he Company has long believed that excess exposure to our talc -- and indeed any talc or mineral dust, can result in pulmonary impairment. We have never claimed otherwise. Non-neoplastic respiratory disease has indeed occurred among our talc miners and to an alarming degree among those exposed prior to the advent of modern dust control systems. ..We have never denied this pneumoconiosis potential." (Tr. 5/11 at 4-104). Similarly, Dr. Brian Boehlecke, testifying as a medical expert for the R.T. Vanderbilt Company, stated: "So my conclusion is that there is a risk of pneumoconiosis from exposure to the type of talc mined and processed at Gouverneur Talc. I believe this is recognized and acknowledged by the company. " (Tr. 5/11 at 4-100).

However although exposures at the mine are attributed to the observed excess in NMRD among exposed workers, the data is insufficient to determine that the non-asbestiform tremolite is the causative agent. The tremolitic talc to which workers are exposed is composed of a variety of different minerals. The non-asbestiform tremolite, although a major constituent, is but one of those minerals. In addition, studies of workers exposed to talcs which do not contain non-asbestiform minerals, have also shown an excess risk of NMRD similar to the excess risk which has been observed among the New York State tremolitic talc workers. (See studies of Vermont Talc workers, Selevan et al; Ex. 479-4 Ex. A). Although the study is too imprecise to conclude that non-asbestiform minerals do not induce pulmonary disease, the study of the Vermont miners does suggest that some agent other than non-asbestiform minerals may be the causative agent in the induction of NMRD. Thus OSHA is unable to conclude that the non-asbestiform content in tremolitic talc is the etiologic agent of NMRD evident at high exposure levels. As a result, OSHA is also unable to conclude that non-asbestiform ATA presents a significant risk of NMRD.

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Occupational Safety & Health Administration
200 Constitution Avenue, NW
Washington, DC 20210

[Text Only]

Regulations (Preambles to Final Rules)

VI. Other Regulatory Issues

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VI. Other Regulatory Issues

a. Regulatory Options

In the proposal OSHA discussed a number of regulatory options to the proposed removal of non-asbestiform ATA from the asbestos standards. Because of OSHA conclusions regarding the health effects evidence, certain of these options are not supported by this rulemaking record.

(1) The first option discussed in the proposal is to continue to regulate ATA in the 1986 asbestos standards. The Agency has determined that on this record, there is a lack of substantial evidence to conclude that non-asbestiform ATA presents a risk of asbestos-related disease to exposed workers of similar incidence or magnitude to the risk created by asbestos. Therefore the evidence does not support regulating non-asbestiform ATA exposure in the same manner as asbestos exposure.

The health data are too uncertain to provide a basis for estimating potential risk from non-asbestiform ATA. This evidence is not sufficient to perform a reasonable independent risk assessment for ATA. Therefore, continuing regulation in the same standard, at a different PEL is not a viable option. OSHA concludes that the evidence and analyses available at this time do not show sufficient similarities between non-asbestiform ATA and asbestos to regulate them together.

(2) Another option was to continue to regulate non-asbestiform ATA under the 1972 asbestos standard. However, the conclusion that the record evidence is insufficient to show that non-asbestiform ATA presents a health risk similar in type and magnitude to asbestos and thus should not be regulated under the 1986 asbestos standards, substantially weakens a major rationale for regulating OSHA under the 1972 asbestos standard as well. The 1972 standard was based on the health effects of asbestos and not the non-asbestiform minerals.

Virtually all of the health data submitted and examined in this rulemaking was not available in 1972. Therefore, the determination of health effects for non-asbestiform ATA based on the record of this proceeding is based on more evidence and superior analyses than in any earlier asbestos rulemaking.

Also, OSHA's regulatory decisions are required by law to be based on "the best available evidence".(OSH Act, Section 6(b)(5)). Although OSHA is not necessarily required to reopen regulatory determinations when new evidence is presented, once a rulemaking proceeding is held, and new, previously unavailable evidence is submitted to that record on important issues OSHA may consider the issue in light of such new evidence. The agency notes that it stated its intention to make a new determination on the current record concerning the health effects of non-asbestiform ATA.

In addition, OSHA finds that removing non-asbestiform ATA from the scope of the 1972 asbestos standard will not pose a significant risk to employees exposed to those minerals. OSHA incorporates here, its previous discussion in the health effects section, which sets forth the Agency's view of the evidence relating to the non-malignant disease potential of ATA. The evidence available implicates talc containing ATA as a causative agent of nonmalignant respiratory disease; however, exposure to ATA alone is insufficiently linked to the production of such disease.

As noted above employees exposed to talc containing ATA will be protected under the Air Contaminants Standard (29 CFR 1910.1001). OSHA believes that the application of the talc limit in the Air Contaminants Standard, for that portion of their exposure which is related to talc, or the standard's mixture formula, will protect exposed employees against a significant risk of nonmalignant disease.

Also, removing the protection of the 1972 asbestos standard from workers exposed to non-asbestiform ATA will not leave them with a significant risk of developing malignant disease. OSHA has found that the available evidence is insufficient to conclude that exposure to non-asbestiform ATA is linked to the development of cancer. The suggestion that long thin fibers of non-asbestiform ATA, which exceed the dimensions for counting asbestos fibers, may have carcinogenic potential was not disproven by the evidence in this proceeding, however, neither was it supported by substantial evidence. Also, even if long, thin non-asbestiform ATA fibers have some carcinogenic potential, the record shows that it is not likely that workers may be exposed to a significant risk from such fibers if the 2 f/cc limit of the 1972 standard is lifted.

First, evidence in the record indicates that, long, thin particles of non-asbestiform ATA occur infrequently. For example, in the industries using tremolitic talc, which are the industries with the highest potential exposure to ATA, there is little evidence that exposures to long, thin particles of non-asbestiform ATA have ever exceeded the 1972 asbestos limit of 2 f/cc. Nor is there evidence that non-asbestiform ATA particles, appearing as a contaminant of any other industrial product (e.g. crushed stone products), attain enhanced dimensions which, if measured, would exceed the 2 f/cc limit of the 1972 standard. Second, there are no dose-response data which can be used to derive a quantitative risk estimate for non-asbestiform ATA as a carcinogen, so OSHA's risk estimate for ATA would be based on qualitative information. The approach formerly considered most promising, basing ATA risk on asbestos risk, has been rejected by the Agency, as explained at length in this document. The Agency believes that no other qualitative approach to assessing non-asbestiform ATA carcinogenic risk is supported by the evidence.

Third, for the industries with the highest potential ATA exposure, which includes those which purchase tremolitic talc as a constituent of products such as ceramic tile and paint, the talc limit, and the mixture formula in the Air Contaminants Standard will apply. OSHA believes that these limits will protect employees against any possible excesses of any

malignant disease as well as non-malignant disease.

Therefore, OSHA finds that removing non-asbestiform ATA from the 1972 standard meets the requirements set out by the Supreme Court for agency deregulation in Motor Vehicles Manufacturers Association v.State Farm Mutual Automobile Insurance Co. (State Farm), 463 U.S. 29, 1983, and is consistent with Agency interpretations of that decision.

(3) The third option discussed in the proposal is to exclude non-asbestiform ATA from the scope of the revised asbestos standards and to initiate a separate 6(b) rulemaking for either industrial talc (tremolitic talc) or non-asbestiform ATA minerals which attain certain dimensions, such as a 3:1 aspect ratio and are longer than 5 um. As stated above, the results of OSHA's examination of the health effects evidence in this proceeding do not provide sufficient data to permit the Agency to estimate the risk, if any, to exposed employees from continued exposure at the 1972 asbestos standard's PEL of 2 f/cc, or at current exposure levels in covered places of employment. There was agreement among participants who addressed the issue that exposure to tremolitic talc at historic levels is associated with excess nonmalignant respiratory disease (see e.g. Dr. Boehlecke, testifying for R.T. Vanderbilt, at Tr. 5/10, pp. 100-101). OSHA's contractor estimated current exposure levels in industries using such talc containing products, even without local exhaust ventilation, as far less then such historic levels.(See CONSAD report, Ex. 465) No additional data concerning exposure levels of such workers was submitted to the rulemaking record. With no basis to estimate risk to exposed employees from talc containing non-asbestiform ATA, OSHA is unable to formulate a proposed standard to protect such workers at this time. As stated above, OSHA believes that the application of the appropriate exposure limits in the Air Contaminants Standard to exposures to constituents of tremolitic talc, and to ATA, will protect employees against significant risks of disease.

If further information is submitted to OSHA in the future, which shows that workers in industries using talc containing non-asbestiform ATA, or other non-asbestiform ATA using industries, are at present risk of developing exposure related disease, OSHA may reconsider this regulatory decision.

(4) The fourth option is to regulate non-asbestiform ATA under a specific listing in the air contaminants standard, including consideration of a listing for non-asbestiform ATA. OSHA has chosen this approach but non-asbestiform ATA will be covered by listing for particulates not otherwise regulated (PNOR) in Table Z-1-A of 1910.1000 [15 mg/m (total dust); 5 mg/m (respirable dust)], which is designed to protect against the significant risk of respiratory effects which all particulates create at higher levels of exposure.

OSHA is not regulating ATA under the listing for talc. OSHA notes that the health evidence concerning the nonmalignant disease potential of talc containing tremolite is not specific to any one component of the product, and there is evidence suggesting that talc, not containing non-asbestiform ATA, also may cause respiratory disease (See for example the preamble to the Air Contaminants Standard, 54 FR at 2526). Accordingly, OSHA revised the PEL for talc to 2 mg/m(3) on January 19, 1989 (54 FR 2332 to 2983, CFR 1910.1000). As talc causes respiratory disease and non-asbestiform ATA as a particulate causes respiratory effects, OSHA concludes that when workers are exposed to mixtures of such dusts with different PELs, the mixture formula applies. Where exposure is to talc containing non-asbestiform ATA, if the employer wishes to avoid separately identifying each component to apply the mixture formula, the entire product may be considered as the substance with the lower PEL.

b. Fiber definition issues

During this rulemaking the NSA and other participants requested that OSHA validate for industry a feasible method of distinguishing asbestos fibers from non-asbestiform particles or other mineral particles which meet the dimensional cutoffs in the asbestos standards. Further, OSHA is asked to define "asbestos" in terms of such differential counting strategy. NSA agrees with the Agency that when the environment is one in which "known asbestos is likely to be the only airborne particle of regulatory concern, it (3:1 aspect ratio criterion) can be an acceptable and economical basis for monitoring worker exposure to substances that pose health risks."(479-1G, p. 22). However, in the crushed stone industry, other particles, NSA insists, will be counted even though they are not asbestos, or even non-asbestiform minerals simply because they have attained aspect ratios of 3:1. OSHA does not believe these scenarios are realistic. The asbestos standards have been in effect since 1972; yet industry presented no data, evidence or testimony that showed the impact of the 3:1 aspect ratio on the crushed stone industry. Producers should know if their products contain asbestos fibers, by surveying deposits, examining hand samples, and doing bulk sampling.

The issue of whether individual fibers of ATA can be identified as to mineral type was further addressed by other witnesses. Dr. Arthur Langer, testifying on his own behalf, noted that "...in some instances single, isolated particles may be impossible to distinguish, i.e. acicular cleavage fragment from asbestiform fibril". (Ex. 517, Tab 5) Dr. Spooner pointed out that identification of an airborne fiber is hindered, when as happens in an industrial hygiene setting "we don't have the opportunity to know where the material is coming from, nor do we have the opportunity to look at a very large population of fibers..." (Tr. 5/8, p. 117-118) NIOSH testified that it was "unaware of any routine analytical methods that can be used to differentiate between airborne exposures to asbestos fibers and non-asbestiform cleavage fragments that meet the microscopic definition of a fiber." (Tr. 5/9, p. 13).

The OSHA reference method may be insufficient in mixed fiber environments to distinguish asbestos from other particles in all cases. However, OSHA believes that currently, producers and users of mineral products feasibly identify asbestos and distinguish it from other mineral fibers or particles. Dr. Langer noted "I would use polarized light microscopy to characterize materials used the work place or characterize mine environments. Someone has to go to some mine or quarry or operation or plant or factory to see whether or not asbestos materials are present, and there are standard techniques to analyze materials and find out whether or not asbestos is present. You could use phase contrast microscopy once you establish what you're dealing with." (Tr. 5/11 at 226). Dr. Langer recommended that OSHA define "asbestos" as certain minerals which display certain properties, which apply to "large aggregates". Such properties are for example, polyfilamentous bundles, made up of unit fibrils, displaying anomalous optical properties, etc. (Id at 227). Dr. Addison commented that for "at the last eight years we've been training a regular number of people in polarized light microscope techniques, ... to recognize the characteristic properties on the macroscopic scale and on the microscopic scale, to come up with what we consider to be a fully authoritative identification of the material as asbestos. It's really not a difficult task." (Ibid).

Dr. Langer also noted that in his knowledge the former Manville Corporation routinely used polarized light microscopy in many of their plants to analyze air samples, where manmade vitreous fiber was mixed with asbestos fiber"(Tr. 5/11, p. 225).

OSHA also notes that differential counting of fibers has been performed by its laboratory and other laboratories in the past. According to the Agency's chief microscopist, identification of

individual fibers is assisted by knowledge of the source of the contaminant, the industrial context, and the skill of the microscopist.(Ex. 410-23).

However, Dr. R.J. Lee, testifying on behalf of the NSA, presented a new analytical method for use in mixed mineral environments. (Ex. 490F) This method was presented as a differential counting procedure for assessing the asbestiform particle population in dusts that include both asbestiform and non-asbestiform particles. Dr. Lee's proposed method uses the current NIOSH 7400 PCM method but in addition incorporates steps to account for particles with widths less than 1 micrometer and particles which are bundles in order to differentiate between those particles which are fibers and those particles which are cleavage fragments.

During the hearing Dr. Lee was questioned as to the validity of this method and whether or not it would alter asbestos counts. In response to this questioning Dr. Lee conducted and submitted the results of a round robin analysis of his proposed method (Ex. 534). In the round robin analysis 6 different labs performed comparisons of particle counts on a variety of different dust samples using the current NIOSH 7400 PCM method and Dr. Lee's proposed method. Although somewhat limited, the results of the round robin analysis indicate that there is little variability between the asbestos fiber counts using the NIOSH method and the asbestos fiber counts using Lee's proposed method. However, according to Dr. Lee, the proposed method allows one to differentiate between asbestos fibers and non-asbestiform cleavage fragments more readily than current differential counting procedures.

Despite the fact that the proposed method appears to provide a feasible means of discriminating between asbestiform fibers and non-asbestiform cleavage fragments, OSHA is reluctant to change its current approved methodology based on such limited data (i.e. one round robin analysis), especially since the Agency notes that changes to the asbestos standards affect a much wider regulated community than participants in this rulemaking. OSHA believes that the adoption of any method would require more extensive testing using a broader range of samples more closely associated with the typical types of occupational exposures covered by the OSHA standards. In addition, considerable expenditures of time and money could be required to insure that labs are adequately training technicians and proficiently using the new method. Before such costs are imposed OSHA believes it would be prudent to better examine the validity of a new method. The Agency notes that the high hazard presented by asbestos exposure requires that any regulatory change affecting counting asbestos fibers err on the side of worker protection. OSHA believes that the burden on employers in affected industries to show that particles are not asbestos is not unreasonable, given the risk presented by undercounting of asbestos, and the claims that asbestos contamination of non-asbestiform products is not common. For these reasons, as well as the fact that OSHA has acknowledged and allowed the use of differential counting with the current method, the Agency does not believe it is either appropriate or necessary at this time to change its current analytical method. The Agency intends to include in its compliance policy governing mixed fiber settings, provision for the introduction of appropriate evidence concerning fiber width, and other relevant evidence to show that particles counted by PCM are not asbestos fibers .

As discussed in the NPRM, rather than change the analytical procedure, Dr. Ann Wylie proposed changing the aspect ratio from 3:1 to 10:1 as a means of discriminating between asbestos fibers and non-asbestiform cleavage fragments (See 55 FR 4951-52). Dr. Wylie reiterated her proposal in the hearings and presented evidence to show that when populations of particles are viewed with respect to the distribution of their aspect ratios, one can easily distinguish between populations of asbestos fibers and populations of cleavage fragments

(Tr. 5/9, pp. 102-107). Dr. Wylie stated that for particles which are greater than 5 um in length, the majority of non-asbestiform particles have aspect ratios less than 10:1 and the majority of asbestos particles (i.e. fibers) have aspect ratios greater than 10:1. Thus she concluded that changing the aspect ratio from 3:1 to 10:1 provides a means of excluding non-asbestiform particles from particles counts while maintaining the same asbestos particle counts one would have obtained using a 3:1 aspect ratio. However as noted above in this discussion, Dr. Spooner points out that Dr. Wylie's observations, as do her definitions of asbestos, apply to populations of particles and the analyst is often not looking at a population of particles when viewing air exposure monitoring samples (Tr. 5/8, pp. 117-118). Moreover as was noted in the proposal, OSHA is reluctant to change its current method based on the findings of one report. OSHA reaffirms its earlier finding and is not, in this rule, changing its dimensional criteria for aspect ratio in its definition of asbestos.

[57 FR 24310, June 8, 1992]

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Occupational Safety & Health Administration
200 Constitution Avenue, NW
Washington, DC 20210